# 5. 510(k) Summary

p. 1 of 2

MAR - 2 2012

**Submitter's Name / Contact Person**

Submitter: TriReme Medical, Inc.
7060 Koll Center Parkway, Suite 300
Pleasanton, CA 94566 U.S.A.

Contact Person: Shiva Ardakani
VP of Regulatory, Quality & Clinical
Phone: (925) 931-1300
Fax: (925) 931-1361

Date Prepared: February 22, 2012

**General Information**

| | |
|---|---|
| Trade Name: | Glider™ PTCA Balloon Catheter |
| Common / Usual Name: | PTCA catheter |
| Product Code: | LOX |
| Classification Name: | Percutaneous transluminal coronary angioplasty (PTCA) catheter [21 CFR 870.5100(a)] |
| Predicate Device: | Monorail Maverick2 and Maverick XL Monorail (Boston Scientific)-P860019<br>EMPIRA Rx PTCA Dilatation Catheter (Creganna Tactx Medical)-K110133 |

**Device Description**

The Glider PTCA Balloon Catheter is a torqueable, rapid-exchange, balloon percutaneous transluminal coronary angioplasty (PTCA) catheter. The device is compatible with commonly used accessories including standard 0.014" coronary guide wires and 6F guide catheters. Overall catheter length is approximately 135 cm.

The distal end of the catheter has a semi-compliant balloon that expands to known diameters and lengths at specific pressures. The balloon has one or two radiopaque markers to assist with positioning. The braid-reinforced shaft and the lubricious hydrophilic coating assist torque transmission. The proximal end of the device is a common PTCA catheter design consisting of a hypotube connected to a plastic hub and strain relief. The hub is used to inflate the balloon and the luer connector is compatible with standard inflation devices. A second lumen within the catheter, intended for guidewire use, extends from the rapid exchange port to the distal tip. The Glider PTCA Balloon Catheter is supplied sterile and intended for single use.

**Intended Use / Indications**

The Glider PTCA Balloon Catheter is indicated for balloon dilatation of the stenotic portion of coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

K111544
p. 2 of 2

**Technological Characteristics/Performance Testing/Substantial Equivalence**

The Glider PTCA Balloon Catheter is substantially equivalent to the predicate device in intended use, indications for use, fundamental scientific technology, and important performance specifications. The device was subjected to the following performance tests according to FDA Guidance *Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (September 8, 2010)*:

- Dimensional Verification
- Balloon Preparation, Deployment & Retraction
- Flexibility & Kink
- Balloon Rated Burst Pressure (RBP)
- Balloon Fatigue
- Balloon Compliance
- Balloon Inflation and Deflation
- Catheter Bond Strength
- Tip Pull Test
- Torque Strength
- Radiopacity
- Catheter Coating Integrity
- Particulate Evaluation
- Biocompatibility Testing Including:
    1. Hemolysis Assay Direct Contact
    2. Hemolysis Assay Extract Method
    3. Platelet & Leucocyte Counts
    4. Partial Thromboplastin Time
    5. Thromboresistance
    6. Complement Activation C3a and SC5b-9 Assay
    7. MEM Elution Assay with L-929 Mouse Fibroblast Cells (Cytotoxicity)
    8. Intracutaneous Reactivity Test
    9. Guinea Pig Maximization Sensitization Test
    10. Materials Mediated Rabbit Pyrogen Test
    11. Acute Systemic Injection Test

No new questions of safety or effectiveness were identified during device testing; therefore, the Glider PTCA Balloon Catheter is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 2 2012

TriReme Medical, Inc.
c/o Ms. Shiva Ardakani
Vice President of Regulatory, Quality & Clinical
7060 Koll Center Parkway, Suite 300
Pleasanton, CA 94566

Re: K111544
Trade Name: Glider™ PTCA Balloon Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: II (two)
Product Code: LOX
Dated: February 15, 2012
Received: February 16, 2012

Dear Ms. Ardakani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

# Indications for Use

510(k) Number (if known): K111544

Device Name: Glider™ PTCA Balloon Catheter

Indications for Use: The Glider PTCA Balloon Catheter is indicated for balloon dilatation of the stenotic portion of coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

M.A. Hollebeek

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111544